IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

TRIANTAFYLLOS TAFAS, Plaintiff, v. JON W. DUDAS, et al., Defendants.	)	Civil Action No. 1:07cv846(L) (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORPORATION, et al., Plaintiffs, v. JON W. DUDAS, et al., Defendants.	)	Civil Action No. 1:07cv1008 (JCC/TRJ)

DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION TO STRIKE

Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively "the USPTO") respectfully submit this reply memorandum in support of their motion to strike exhibits filed by Plaintiff Triantafyllos Tafas, *Amicus Curiae* Ron D. Katznelson ("Katznelson"), and *Amici Curiae* Polestar Capital and Norseman Group ("Polestar") that are not contained in the administrative record, along with the portions of their briefs that rely on those exhibits.

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INTRODUCTION

In moving to strike extra-record material that Plaintiff Tafas and *Amici* Katznelson and Polestar attached to their summary judgment filings, the USPTO noted that this Court has already observed that "[i]n applying the arbitrary and capricious standard, 'the focal point for judicial review should be the administrative record already in existence.'" The USPTO further noted that although this Court recognized that there are some exceptions to this rule, the Court concluded after considering each of Tafas's arguments that "Tafas has not made a sufficiently strong or substantial showing of incompleteness to overcome the presumption that the USPTO properly designated the administrative record." This Court further considered whether it was appropriate to go beyond the administrative record to consider Tafas's claim under the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601-12. The Court held that it was not, finding that the record was "sufficient for this Court to determine whether the USPTO made a 'reasonable, good-faith effort' to comply with the RFA's procedural requirements." For these reasons, the USPTO urged this Court to strike all extra-record material upon which Tafas, Katznelson, and Polestar seek to rely for their arbitrary and capricious and/or RFA arguments.

Tafas now responds with an opposition memorandum that – once again – misapprehends the scope of judicial review under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq., ignores this Court's prior conclusions regarding the adequacy of the administrative record, and inappropriately attempts to reargue the merits of his arbitrary and capricious claim, as well as his claim under the RFA. In the end, Tafas fails to demonstrate that any of the extra-record material upon which he relies falls within a recognized exception to the general rule that judicial review under the APA is confined to the administrative record.

Polestar has also filed an opposition memorandum, again failing to recognize that it is not a party to this litigation. Polestar seeks to raise and reiterate its own arguments, which the parties themselves did not make in their summary judgment motions. As this Court recognized from the outset of this litigation, it is improper for a non-party to introduce arguments outside of those raised by the parties. Polestar compounds this error by attempting to introduce literally hundreds of pages of extra-record materials that the parties themselves do not even cite. Further mistaking itself for a party, Polestar has retained its own expert to proffer additional extra-record material and opinions outside of those raised by the parties. Polestar's memorandum also suffers many of the same defects as Tafas's memorandum, which are further detailed below.

Finally, Katznelson has joined the fray by filing his own opposition memorandum. Like Tafas, Katznelson's opposition memorandum also reflects a misapprehension of the proper scope of judicial review under the APA and ignores this Court's prior decision regarding the adequacy of the administrative record and the procedural nature of the RFA. For the reasons set forth herein and in the USPTO's opening memorandum, this Court should strike the extra-record material identified in its Motion to Strike and any subsequently-filed exhibits that suffer the same infirmities.

I. THE COURT SHOULD STRIKE ALL EXTRA-RECORD MATERIAL RELATED TO THE CLAIM THAT THE FINAL RULES ARE "ARBITRARY OR CAPRICIOUS" UNDER THE APA

The majority of Tafas's and Katznelson's opposition memoranda fail to apprehend the Supreme Court's repeated holding that in conducting APA review, "the focal point for judicial review should be the administrative record already in existence, not some new record initially made in the reviewing court." Camp v. Pitts, 411 U.S. 138, 142 (1983); Fla. Power & Light Co.

v. Lorion, 470 U.S. 729, 743-44 (1985) ("The task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court."). This Court has already recognized the limited review afforded under the APA. Relying on Camp, this Court indeed has twice made the same observation in this very case. Tafas v. Dudas , — F. Supp. 2d —, 2008 WL 112043, at *3 (E.D. Va. Jan. 9, 2008) ("Tafas II") ("In applying the arbitrary and capricious standard, 'the focal point for judicial review should be the administrative record already in existence.'"); Tafas v. Dudas, 511 F. Supp. 2d 652, 662 (E.D. Va. 2007) ("Tafas I") ("Generally, 'judicial review of agency action pursuant to the APA is confined to the agency's administrative record.'") (quoting Am. Canoe Ass'n, Inc. v. U.S. Envtl. Prot. Agency, 46 F. Supp. 2d 473, 474 (E.D. Va. 1999). Even Tafas at least appears to recognize that in APA cases, "'the administrative record provides the complete factual predicate for the court's review.'" Tafas Mem. at 3 (quoting Krichbaum v. Kelley, 844 F. Supp. 1107, 1110 (W.D. Va. 1994), aff'd 61 F.3d 900 (4th Cir. 1995) (emphasis added); id. at 4 ("In order, therefore, to prevail by summary judgment, the parties in an APA case, 'must point to facts in the administrative record – or to factual failings in that record – which can support [their] claims under the governing legal standard.'") (quoting Krichbaum, 844 F. Supp. at 1110); see also Tafas Opp. to Mot. to Stk. at 4 ("A rule must be set aside if data . . . in the rulemaking record demonstrates that the rule constitutes such an unreasonable assessment . . . as to be arbitrary and capricious.") (citing Thompson v. Clark, 741 F.2d 401, 405 (D.C. Cir. 1984); id. ("Internally contradictory agency reasoning renders resulting action arbitrary and capricious.") (citing Defenders of Wildlife v. U.S. Env'l Prot. Agency, 420 F.3d 946, 959 (9th Cir. 2005). In light of this limited review, this Court should strike any material that is not already included in the 10,000-page administrative record in this case and does not fall within at least one of the three limited exceptions to supplementing the administrative record. Cf. Am. Canoe Ass'n, 46 F. Supp. 2d at 475 (describing the limited circumstances where supplementation of the record is appropriate).

Tafas and Katznelson both cite Motor Vehicle Mfrs. Ass'n of U.S., Inc., v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983), in an effort to justify their reliance on extra-record materials. See Tafas Opp. at 2, 14, 15. Specifically, Tafas (as well as Katznelson) ostensibly contend that State Farm allows the District Court in an APA action to consider evidence outside the administrative record any time a plaintiff asserts that the relevant agency overlooked "important aspects of the problem." See, e.g., id. at 2 (citing State Farm, 463 U.S. at 43); see also Katznelson Opp. at 4-8. Tafas and Katznelson have failed to apprehend, however, that the question in State Farm review is whether the agency failed to consider factors that were actually presented to it at the time of the challenged decision – not factors that are found in materials submitted to the Court during the course of litigation. Again, the scope of judicial review in APA cases is limited to the administrative record that was before the agency. The reasons underlying this well-settled proposition are clear: "if a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision." Walter O. Boswell Mem'l Hosp. v. Heckler, 749 F.2d 788, 792 (D.C. Cir. 1984). "Review is to be based on the full administrative record that was before the Secretary at the time he made his decision." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420 (1971) (emphasis added); see also Environmental Defense Fund, Inc. v. Costle, 657 F.2d 275, 284 (D.C. Cir. 1981). For this Court to review more than the information before the

USPTO at the time of its rulemaking risks "requiring administrators to be prescient," see Boswell Mem'l Hosp, 749 F.2d at 792, "allowing them to take advantage of post-hoc rationalizations," id., or invites this Court to substitute its own judgment for that of the agency, see Overton Park, 401 U.S. at 416, an impermissible result. Tafas's and Katznelson's reliance on State Farm, therefore, provides no justification for this Court to consider materials that fall outside the 10,000-page administrative record in this case. To the contrary, absent the existence of any of the three recognized exceptions to supplementing an administrative record, well-settled APA jurisprudence affirmatively restricts judicial review to only those materials that were before the agency at the time of the challenged decision.

Contrary to the approach this Court has already adopted in this case, Polestar and Katznelson list *eight* circumstances in which supplementation of the record is appropriate. See Polestar Opp. at 2-4; Katznelson Opp. at 4-5. Neither the Fourth Circuit, nor this Court have ever adopted these multiple additional exceptions to the rule limiting judicial review to the administrative record. These extraordinarily broad exceptions collectively swallow the general rule. For example, nearly every APA case subjects the "procedural validity" of an agency's decision to scrutiny. Adoption of these broad categories, therefore, would effectively eviscerate the concept of limited judicial review under the APA.

Tafas asserts that he should be permitted to rely on extra-record material to establish that the Final Rules are arbitrary and capricious[1] because "common sense and experience dictates that no administrative agency is going to affirmatively state that its rule making was promulgated in disregard of important facts, without principle or in bad faith." Tafas Opp. at 4. This argument borders on the absurd. Whether the USPTO – or any Federal agency – affirmatively states that it acted consistent with applicable law is absolutely irrelevant. The USPTO, of course, has never argued in this case that such a statement would suffice to uphold the Final Rules under APA review. Rather, the USPTO noted that to satisfy judicial review, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." State Farm, 463 U.S. at 43 (internal quotation marks omitted). If the agency's decision was "based on a consideration of the relevant factors," and there has not been a "clear error of judgment," then the agency action must be upheld. Id. (internal quotation marks omitted). Here, the USPTO provided the "whole record," see 5 U.S.C. § 706, in connection with the challenged rulemaking. That record included more than 4,000 pages of data and more than 500 public comments, which by their very nature reflected both positive and negative appraisals of the rules. To the extent Tafas believes that the Final Rules are arbitrary and capricious, it is incumbent upon him to identify evidence within the administrative record indicating that the USPTO overlooked important factors, improperly considered other factors, or offered explanations contrary to evidence in the record. Cf. State Farm, 463 U.S. at 43. Accordingly, the introduction of new materials outside the record that the Office never had an opportunity to consider in the first instance is entirely improper.

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[1] Tafas inappropriately cites Black's Law Dictionary for the definitions of "arbitrary" and "arbitrary and capricious." These legal terms of art, as used in the APA, have very well-settled definitions, elaborated through decades of case law. Cf. Yates v. United States, 354 U.S. 298, 319 (1957) (concluding that it would not "assume that Congress . . . used the

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words 'advocate' or 'teach' in their ordinary dictionary meanings when they had already been *construed as terms of art* carrying a special and limited connotation.") (emphasis added); United States v. SKW Metals & Alloys, Inc., 195 F.3d 83, 90 (2d Cir. 1999) (noting that dictionary definitions lose their interpretive value where statutory words and phrases constitute "terms of art" or are given particular meaning by the pertinent statutory scheme).

Tafas next asserts that if this Court were to apply "the USPTO's twisted and extreme logic," that is, limiting judicial review to the administrative record, then Tafas would have to accept any proposition (no matter how absurd) asserted by the USPTO. See Tafas Opp. at 5. Tafas fails to acknowledge that this case – just as the overwhelming majority of APA cases – is not about objective, empirical certainties like "does 2+2=5" or "is the earth is flat." Id. Rather this case involves the USPTO's efforts to: confront issues regarding the timeliness, efficiency, and quality of patent examination; develop rules to promote the improvement of patent examination; weigh the myriad of factors presented to it from the public and other governmental organizations; and reach conclusions about the best procedures for the agency to follow to achieve its goals. These are the decisions that are subject to review by this Court under the APA – not whether 2+2=5. This Court must review the administrative record and determine whether the USPTO reached its decisions in a manner that is consistent with the law.

Tafas next asserts – without citation to any judicial precedent – that the Federal Rules of Evidence provide an additional vehicle to supplement the administrative record. See Tafas Opp. at 6 (citing Fed. R. Evid. 401, 402, 607, 611(b), 613(b)). Tafas ostensibly argues that a Court may consider extra-record material in an APA case whenever the material appears "legally relevant" – irrespective of whether the material was before the agency at the time of the challenged decision. This over-broad concept of APA review lacks any legal support, and is entirely inconsistent with Supreme Court precedent. See, e.g., State Farm, 463 U.S. at 43. Indeed, "relevance" alone is not the test for what belongs in an administrative record. Rather, an administrative record must contain "all documents and materials directly or indirectly considered by the agency." Bar MK Ranches v. Yuetter, 994 F.2d 735, 739 (10^{th} Cir. 1993). As set forth above, this Court's role on review is not to weigh the evidence pro and con or to opine how materials that were never before the agency would have affected the agency's decision, but to determine whether the agency decision "was based on a consideration of the relevant factors and whether there was a clear error of judgment." Id. Thus, when the administrative record demonstrates that the agency considered appropriate factors and articulated a rational relationship between the facts found and the choice made, its decision is not arbitrary and capricious. Id. The introduction of materials that are "relevant" or are used for "impeachment," but which were never before the agency in the first instance, improperly invites this Court to substitute its own judgment for that of the agency. This Court should decline Tafas's invitation.

Tafas next asserts that the introduction of extra-record material into this case is appropriate to "explain or interpret the administrative record as well as to provide the Court with the necessary context and understanding to consider APA challenges." Tafas Opp. at 6-7. The USPTO recognizes that this Court has held that supplementing the administrative record in an APA case is appropriate in limited circumstances such as where it is necessary to "explain or clarify technical terms or other difficult subject matter included in the record." See Tafas I, 511 F. Supp. 2d at 662 (citing Am. Canoe Ass'n, 46 F. Supp. 2d at 475).[2] Tafas's memorandum cites numerous cases and includes substantial block quotes that support this unremarkable and largely uncontested proposition. See Tafas Opp. at 7-11. Tafas fails to even articulate, however, which aspects of the administrative record in this case are so "technical" or "difficult" that this Court needs assistance to determine whether or not the Final Rules are arbitrary and capricious. Furthermore, Tafas has not articulated how the extra-record materials upon which he relies in support of his arbitrary and capricious argument, see Tafas Mem. at App. C, Exs. 4-27, 44, "explains or clarifies" any putative "technical terms" or "difficult subject matter" in the administrative record. In other words, Tafas has not demonstrated that these extra-record materials fall within any of the limited exceptions to the general rule that APA judicial review is confined to the administrative record.[3]

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[2] Tafas cites Esch v. Yeutter, 876 F.2d 976, 991 (D.C. Cir. 1999) for the proposition that there are eight exceptions to the general rule that judicial review in APA cases is confined to the administrative record. See Tafas Opp. at 8. As the USPTO noted in its opening memorandum, this Court has consistently applied American Canoe Ass'n, which recognizes only three exceptions to the general rule. See Tafas I, 511 F. Supp. 2d at 662.

Finally, Tafas asserts that this Court may consider extra-record material to make an "independent assessment" of his constitutional claims. The USPTO recognizes that this Court has noted that "in adjudicating constitutional claims under the APA, courts have permitted plaintiffs to submit evidence that was not part of the administrative record." Tafas II, 2008 WL 112043, at *12. Tafas fails to acknowledge, however, that this Court has already held that the "administrative record is sufficient for the Court to render a final decision as to the constitutionality of the Final Rules under the Patent Clause." Id. In any event, Tafas is not even using the extra-record material in support of his constitutional claims. Rather, he cites the majority of this material in support of his argument that the Final Rules are arbitrary and capricious. Accordingly, the mere presence of his constitutional claim does not provide him with an appropriate basis upon which to rely on this extra-record material.[4]

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[3] To the extent that Tafas relies on Dr. Richard Belzer's extra-record material in support of his arbitrary and capricious claim, this material nevertheless fails to satisfy any of the recognized exceptions. As an initial matter, as explained in the USPTO's reply memorandum, see USPTO Rep. Mem. at 23-24, Tafas's citation to Dr. Belzer's declaration improperly seeks to incorporate arguments raised solely by *amici*. This Court has already admonished that it will "not consider legal issues or arguments that were not also raised by Plaintiffs." Tafas I, 511 F. Supp. 2d at 660-61. Furthermore, much of the declaration is directed to the USPTO's purported failure to satisfy its various obligations under the Paperwork Reduction Act, 44 U.S.C. § 3501, et seq., and Executive Order 12,866. As the USPTO has already explained, the USPTO's compliance (or alleged lack thereof) with these regulatory mandates is irrelevant to this Court's review of the Final Rules under the APA. See USPTO Tafas Opp. at 15-16.

II. THE COURT SHOULD STRIKE ALL EXTRA-RECORD MATERIAL SUBMITTED BY TAFAS AND KATZNELSON RELATED TO THE USPTO'S RFA CERTIFICATION

In its opening memorandum, the USPTO urged this Court to strike the declaration of Dr. Robert Fenili and several of Katznelson's exhibits because they impermissibly introduce into the record materials that were not before the USPTO when it promulgated the Final Rules and are, as a matter of law, irrelevant to Tafas's claim under the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601-612.[5] As the USPTO noted, this Court has already held that Tafas failed to demonstrate that the administrative record in this case needs to be supplemented for purposes of resolving his RFA claim. Indeed, this Court – like other Courts around the country – recognized first that the RFA imposes only procedural requirements on an agency, and that an agency need only "put forth a 'reasonable, good faith effort'" to fulfill these requirements. Tafas II, 2008 WL 112043 at *9 (quoting U.S. Cellular Corp. v. FCC, 254 F.3d 78, 88 (D.C. Cir. 2001)).

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4 Tafas briefly asserts that consideration of extra-record material is appropriate when it takes the form of "newly-discovered evidence." Tafas Opp. at 12. Tafas has not identified which materials he contends fall within this exception. Furthermore, this "newly-discovered evidence" exception recognized in United States v. Akzo Coatings of America, Inc., 949 F.2d 1409, 1428 (6th Cir.1991), arises in the context of a District Court reviewing adjudicatory proceedings before an agency – not a rulemaking. See id.; see also Sierra Club v. U.S. Army Corps of Engineers, 935 F. Supp. 1556, 1567 (S.D. Ala.1996). Finally, this exception has not been adopted by this Court.

5 Tafas notes that the USPTO did not move to strike Dr. Belzer's declaration in connection with his claims that the USPTO failed to comply with the RFA. As Tafas recognizes, the USPTO did in fact move to strike Dr. Belzer's declaration regarding his arbitrary and capricious claim. See Tafas Opp. at 12-13. In any event, at the time the USPTO filed its motion to strike Tafas had not yet attempted to adopt the arguments raised by *amicus* Polestar and Dr. Belzer for purposes of his RFA claim.

Importantly, this Court then held that "the existing administrative record is sufficient" for "this Court to determine whether the USPTO made a 'reasonable, good faith effort' to comply with the RFA's procedural requirements." Id. at *9 (citing 72 Fed. Reg. 46830-35; A07203-A08329); see also Little Bay Lobster Co. v. Evans, 352 F.3d 462, 470-71 (1st Cir. 2003) (conducting RFA review on the administrative record).

In response, Tafas first accuses the USPTO of "mixing apples and oranges" and notes that this Court's comments regarding the adequacy of the record for purposes of resolving his RFA claim are not the law of the case or dispositive of the merits of his RFA claim. The USPTO does not contend – and never has contended – that the Court has already disposed of the RFA claim on the merits. The Court has, however, reached a decision that it need not go beyond the administrative record to decide the RFA claim on summary judgment. This decision is now the law of the case. To the extent Tafas asserts that this Court has not expressly concluded that "the existing administrative record is sufficient" for "this Court to determine whether the USPTO made a 'reasonable, good faith effort' to comply with the RFA's procedural requirements," he fails to articulate any alternative interpretation of the Court's holding in that regard. In view of the Court's clear and unambiguous ruling that the existing administrative record is sufficient to conduct a review of Tafas's RFA claim, the Court should strike all the extra-record material upon which Tafas, Katznelson, and Polestar rely.

Tafas next contends that the introduction of extra-record material in connection with his RFA claim is appropriate to demonstrate that the USPTO's certification was based upon unreasonable assumptions and that the USPTO failed to consider relevant factors. See Tafas Opp. at 13-14. As the USPTO demonstrated in its reply memorandum, the extra-record material upon which Tafas relies in support of his RFA claim merely criticizes the particular economic models the Office used to support its RFA certification. These criticisms, however, are substantive in nature and is thus irrelevant. Tafas II, 2008 WL 112043 at *9 (holding that "[t]he RFA 'imposes no substantive requirements on an agency; rather, its requirements are 'purely procedural' in nature.'") (quoting Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric., 415 F.3d 1078, 1100 (9th Cir. 2005)); Alenco Commc'ns Inc. v. FCC, 201 F.3d 608, 625 (5th Cir. 2000) ("The RFA is a procedural rather than substantive agency mandate"). Because the administrative record amply demonstrates all the efforts the Office undertook in connection with the procedural requirements mandated by the RFA, there is no basis to supplement the record.

To the extent Tafas and Katznelson assert that extra-record material is appropriate to explain or clarify technical terms or difficult subject matter, their arguments must fail. Although some of the patent law and patent application procedures at issue in this case are technical in nature or may properly be characterized as difficult subject matter, the question of whether the USPTO complied with its procedural obligations under the RFA is not. Indeed, as the USPTO has argued throughout this litigation, the RFA essentially requires only that the USPTO consider alternatives that lessen the economic impact regulations will impose on small entities and explain why significant alternatives were not selected. See, e.g., Alenco Comm'n Inc., 201 F.3d at 625; see also N.C. Fisheries Ass'n, Inc. v. Gutierrez, 2007 WL 2331048, *24 (D.D.C. Aug. 17, 2007) ("a court reviewing a RFA-based challenge does not evaluate whether the agency got the required analysis right, but instead examines whether the agency has followed the procedural steps laid out in the statute"). There is nothing overly technical or exceptionally difficult about this inquiry such that extra-record, expert material is appropriate.

Tafas next devotes a substantial portion of his memorandum arguing the merits of his RFA claim. See Tafas Opp. at 15-20. The USPTO has exhaustively responded to these arguments and has affirmatively demonstrated that it has satisfied its obligations under the RFA. Because this memorandum is an inappropriate forum in which to reassert these merits-based arguments, and in the interest of economy, the USPTO respectfully refers the Court to its prior briefing on these issues.

Tafas next asserts that this Court should not strike his declaration or the declaration of Michael Rueda. As an initial matter, the USPTO has not moved to strike Tafas's declaration. Instead, the USPTO has moved to strike – for all the reasons contained in this memorandum and its Motion to Strike memorandum – the extraneous, extra-record material that is appended to his declaration. Further, the USPTO notes that this Court should disregard Tafas's declaration to the extent he seeks to rely upon it to establish that the Final Rules are arbitrary and capricious. Rueda's declaration must be stricken because it does not fall within any of the recognized exceptions to supplementing the administrative record and serves no other purpose but to authenticate extra-record materials that ought not be considered by this Court.

Finally, Tafas asserts that the cases cited by the USPTO, which stand for the proposition that courts should strike extra-record material that was not before the agency at the time of the challenged decision, are distinguishable in that none of them involved claims under the RFA. Significantly, Tafas fails to distinguish these cases relative to the APA's arbitrary and capricious principles, further demonstrating that this Court's APA review is limited to materials contained in the existing administrative record. Tafas also fails to articulate how the holdings in these cases would be any different under the RFA. They should not. Because the RFA requires courts to review what efforts an agency took to comply with its procedural obligations – one of which is to consider, as the USPTO did (see A08301-03), significant alternative proposals submitted by the public during the notice and comment period, 5 U.S.C. § 603(a)(5) – this Court must focus only on what was before the agency at the time of its rulemaking. Because the administrative record amply reflects all of the material that was before the Office at the time of its rulemaking and all of its efforts to comply with the RFA, this Court must confine its review to the administrative record. Cf. Tafas II, 2008 WL 112043 at *9 (concluding that the administrative record in this case is "sufficient for this Court to determine whether the USPTO made a 'reasonable, good-faith effort' to comply with the RFA's procedural requirements.").

III. Polestar's Meritless Assertions that the Administrative Record Is Incomplete Are an Impermissible Attempt to Re-Litigate Issues that the Plaintiffs Have Repeatedly Lost

As this Court is aware, the question of whether the administrative record is incomplete has been litigated by the parties over and over for months. The issue was first litigated before Magistrate Judge Jones, when both Tafas and the GlaxoSmithKline Plaintiffs filed several motions seeking to show that the administrative record was incomplete. Dissatisfied with Judge Jones's ruling to the contrary, Tafas took objections to this Court, which held that "Tafas has not made a sufficiently strong or substantial showing of incompleteness to overcome the presumption that the USPTO properly designated the administrative record." Id. at *7. Tafas has challenged that ruling once again through a meritless motion for reconsideration.

Waiting in the wings, Polestar – an *amicus* – now seeks to upset the Court's settled ruling by making new arguments, never before put forth by the parties, to show the record to be incomplete. This is not only an impermissible role for an *amicus* to play, but also an inappropriate time for the *amicus* to play it. The Court has now proceeded to the merits of the case, when it must decide whether the existing administrative record supports the agency's action under the deferential State Farm standard.

Polestar nonetheless asserts that this Court may consider its extra-record material because the USPTO's subsequent supplementation of the administrative record demonstrates that the record is not complete. Polestar also outrageously asserts that the incomplete record indicates that "many documents were 'deliberately or negligently omitted'" from the record, despite absolutely no evidence of deliberate misconduct. See Polestar Opp. at 4-9. Polestar has dramatically overstated the significance of the USPTO's subsequent supplementation and mischaracterized the reason for the supplementation. As a preliminary matter, it should be noted that the two plaintiffs and **twenty** amici filing memoranda in opposition to the USPTO were only able to identify two minor omissions (what turned out to be eleven comments and one of the two initial RFA certifications) in the administrative record that the USPTO promptly cured. Considering that the administrative record in this case is nearly 10,000 pages in length, the inadvertent omission of only a few documents in no way suggests that the USPTO was "negligent" in compiling the record or that it was "deliberately" withholding material. Furthermore, such a minor omission – which has since been cured – is not sufficient grounds for this Court to conclude that the Final Rules are arbitrary and capricious. Cf. Connecticut v. Daley, 53 F. Supp. 2d 147, 159 n.10 (D. Conn. 1999) (holding that documents inadvertently omitted from administrative record did not render agency's action arbitrary or capricious); TOMAC v. Norton, 193 F. Supp. 2d 182, 195 (D.D.C. 2002) ("The fact that TOMAC has identified three documents that it asserts should have been included in the administrative record – among 5,000 pages of information obtained through FOIA – is not strong evidence of bad faith or an incomplete record.").

Polestar's assertion that the subsequently supplemented material raises issues that were not considered by USPTO lacks merit. See Polestar Opp. at 4-5. The comments to which Polestar refers were all raised by Heritage Woods, Inc. (SA004-35). Significantly, the USPTO expressly addressed the following items in its Federal Register notice:

- Cause of backlog being examiner and supervisory failures, see 72 Fed. Reg. at 46762-63, 46819 (comments 53, 288);
- Admonition that the USPTO cannot compromise inventors' rights for mere administrative convenience as noted in In re Weber, 580 F.2d 455 (C.C.P.A. 1978), see 72 Fed. Reg. at 46757, 46814 (comments 38, 265);
- Revenue impact, see 72 Fed. Reg. at 46757 (comment 39);
- Productivity and compensation metrics, see 72 Fed. Reg. at 46762-63, 46790, 46817-18, 46818 (comments 53, 179, 279, 281)
- Burdens imposed on most deserving applications, see 72 Fed. Reg. at 46788, 46791, 46798 (comments 166, 184, 219);
- Patent term, see 72 Fed. Reg. at 46793 (comment 196); and
- Alternatives, see 72 Fed. Reg. at 46817-18, 46818-19, 46819, 46819-20, 46821, 46823-24 (comments 279, 284, 288, 289, 298, 311)

In short, the issues raised by Heritage Woods were also raised by other comments. The response to such comments in the Federal Register therefore will not always use the precise vernacular as that used by Heritage Woods. In light of the foregoing, it is clear that the USPTO considered these particular issues that Heritage Woods has raised.

Further, there were many comments made only by Heritage Woods:

- querying whether extensions of time would be available for compliance with 37 CFR 1.78(f)(1), see 72 Fed. Reg. at 46781 (comment 120), (SA016-17);

- asserting that it is beyond the USPTO's authority to require more than a terminal disclosure to overcome double patenting, see 72 Fed. Reg. at 46785 (comment 144), (SA016);

- asserting that multiple applications with indistinct claims are a necessary and desirable component of US Patent law, see 72 Fed. Reg. at 46786 (comment 158), (SA015);

- asserting that the USPTO is resurrecting old provisions of the rules, see 72 Fed. Reg at 46806 (comment 248), (SA024); and

- the patent term comment above, see 72 Fed. Reg. at 46793 (comment 196), (SA025);

Because Heritage Woods alone made the above comments, and because these comments appear in the Federal Register, it is clear that the USPTO expressly considered these comments even though they were inadvertently omitted from the administrative record.

Polestar next asserts that the USPTO "negligently" or "deliberately" failed to include in the administrative record its Initial Regulatory Flexibility Act ("IRFA") certification regarding the claims rule. As the USPTO noted in its amended certification of the administrative record, see Dkt. No. 248, the information contained in this IFRA certification is included in the existing administrative record. See Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61, 66 (A00006). The USPTO explained that the first paragraph of the document is conveyed in substance in the referenced Federal Register notice, and the second through fourth paragraph of the documents were produced verbatim. Id. Thus any assertion that the USPTO attempted to "hide" its certification from the public or any other governmental entity is patently absurd and lacks any factual basis in the record.

Polestar next asserts that "a number of inter-agency communications" appear to be missing from the administrative record. Specifically, Polestar argues that the Final Rules package that USPTO submitted to OMB on April 10, 2007 were "changed" from the Final Rules that OMB concluded reviewing on July 9, 2007. See Polestar Opp. at 7. Polestar further cites to EO 12,866, §6(a)(4)(E)(ii) for the proposition that USPTO is required to document and disclose to the public the changes USPTO made as a result of OMB review. As a preliminary matter, the correct cite that Polestar is referencing is §6(a)(3)(E)(iii), which says that "after the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA." In any event, no changes were made in the Final Rules at OMB's insistence. Further, section 6(a)(3)(E)(iii) of the Executive Order does not require, on its face, that any documents be placed into the administrative record. Even if it could be read in this manner, in the present situation, because there were no changes made at OMB's request, there would have been no documents to place in the record. Finally, the Executive Order does not alter the longstanding proposition that (1) drafts and (2) deliberative, inter-agency communications do not belong in the administrative record in the first instance.

Polestar next asserts that several of the eighteen "town hall" presentations presented by the USPTO are absent from the record, including recorded public speeches in which USPTO officials provided comments on the proposed rule changes. See Polestar Opp. at 8. Contrary to Polestar's baseless assertions, the USPTO held only four Town Hall meetings (not eighteen), and all four of those Town Hall slide presentations appear in the administrative record. The USPTO did not record, by transcription or otherwise, any Town Hall meeting or the two specific speeches that Polestar mentions (Whealan on Feb. 17, 2006 and Doll on April 4, 2006). The USPTO is not required, as part of its administrative record, to scour the world to find anyone who made a recording of those speeches in order to put them in the administrative record. No slide presentation from April 4, 2006 therefore is in the administrative record. In any event, Polestar simply cites to an oral exchange between Doll and a member of the audience on that date, not to any slide show.

The remainder of Polestar's opposition memorandum asserts, in excruciating detail, why it believes that this Court should consider each exhibit the USPTO moved to strike. The USPTO's opening memorandum, however, establishes why each of these exhibits should be stricken, and under no circumstances, be made a part of the administrative record. In general, as the USPTO has repeatedly explained, the Final Rules must be examined on the basis of the existing administrative record, see Camp v. Pitts, 411 U.S. at 142; Fla. Power & Light Co. v. Lorion, 470 U.S. at 743-44, and these materials relate to arguments that are outside the scope of the arguments raised by the parties, Tafas I, 511 F. Supp. 2d at 660-61.

CONCLUSION

For the foregoing reasons, the Court should strike the extra-record materials identified above and the portions of the briefs that rely on them.

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Respectfully submitted,

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